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EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1618

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09/01/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/995,358	Applicant(s) ZECCHINO ET AL.	
	Examiner BLESSING M. FUBARA	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-10,12-16,18,19 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-10,12-16,18,19 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/30/2008</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The examiner acknowledges receipt of IDS filed 12/30/08, request for extension of time, remarks and non-compliant amendment filed 4/13/09 and compliant amendment filed 6/22/09. Claims 2 and 20 are canceled. Claims 1, 6, 7, 19 and 21 are amended. Claims 1, 3-10, 12-16, 18, 19 and 21 are pending.

Response to Arguments

Previous rejections that are not reiterated herein are withdrawn in view of the amendment to the claims and in view of applicant's citation of *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (FED. Cir. 1983) in which it was held that "exceeding about 10%" is definite under 35 USC 112, 2nd.

Applicant has constantly used the term "Appellant" in the remarks filed 4/13/09. It is, however, respectfully brought to applicant's attention that the response filed 4/13/09 and 6/2/09 is not an Appeal Brief.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1, 3, 6-10, 12-15, 18, 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wheeler (WO 97/32559) in view of Clariant product brochure or in view of Beerse et al. (US 6,294,186) for reasons of record and modified herein to remove canceled claims 2 and 20 from the rejection.

Wheeler teaches the preparation of bi-liquid foam by combining oil-based bi-liquid foam and an aqueous gel, gelling polymer and the pH is adjusted to less than or equal to 7 with citric acid (page 6, lines 1-10 and 20-23 and examples 1-4) with the composition meeting claims 3, 13.

Wheeler teaches cosmetic or pharmaceutical composition comprising a stable dispersion that comprises oil-based bi-liquid foam and an aqueous gel (abstract) with the bi-liquid foam meeting the biliquid foam of the claims. The oil-based bi-liquid foam of Wheeler is from 1% to 80% by weight of the total formulation (lines 1-4 of 4th full paragraph of page 3) meeting claims 9, 10, 14, 15. The composition Of Wheeler also comprises silicone oils wherein the oils can be cyclomethicone, dimethicone, dimethicone copolyol, lanolin and dimethiconol (5th full paragraph of page 3) meeting claim 8. The composition of Wheeler uses low levels of surfactant (second full paragraph of page 3) and Wheeler teaches a formulation further comprising from 0.05% to 0.5% of surfactant and active ingredient in the aqueous or oily phase (lines 4-7 of 4th full paragraph of page 3) with this amount meeting the requirements for the surfactant amounts in

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claims 1, 12 and 19. Wheeler teaches that the low level of surfactant incorporated into the formulation comprises quaternary ammonium sulfonium salts, amphoteric surfactant, anionic surfactant, alpha-olefin sulfonate, and ester-linked sulfonate (3rd full paragraph of page 4). Wheeler exemplifies compositions that are adjusted to pH 5.5 (example 2), pH 6.5 (examples 1, 3) and pH 7 (example 4) which suggests that pH of the solutions to be at less than or equal to 7 such that it would have been obvious to prepare the compositions at pH of less than or equal to 7 meeting the requirements of claims 1, 12 and 19. The aqueous phase contains polymer or gum such as alginate gums or their salts, guar gum, locust bean gum, xanthan gum, gum acacia, gelatin, hydroxymethylcellulose or its sodium salt, hydroxyethyl- cellulose, hydroxypropylcellulose, carboxymethylcellulose, bentonites, magnesium aluminum silicates, "Carbomers" (salts of cross-linked polymers of acrylic acid), or glyceryl polymethacrylates or their dispersions in glycols, or any appropriate mixture of any of these polymers and gums in an amount between 0.05-20% (page 4, first full paragraph), all of which are gelling agents having the ability to gel compositions and with points within the disclosed amount touching points within the recited amount of 0.01 to 10% and thus meets requirement for amount of gellant in claims 1, 6, 12, 18, 19 and 21. The aqueous phase also contains salt (first full paragraph of page 5) meeting the requirement for the present of salt in claims 1, 12 and 19. Wheeler is silent on the amount of salt to be used, regarding the percent amounts of salt, it would be obvious to use appropriate amount of salt that would be provide desired pearlescence and luster to the gelled composition.

However, Wheeler does not use polymeric sulfonic acid as a gelling agent. However, Clariant product brochure teaches Aristoflex AVC or copolymer of polyacryldimethyltauramide

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and vinylformamide gelling agent for aqueous systems and thickening agent for oil-in-water emulsions. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare the bi-liquid foam by gelling the composition with alginate gums or their salts, guar gum, locust bean gum, xanthan gum, gum acacia, gelatin, hydroxymethylcellulose or its sodium salt, hydroxyethyl cellulose, hydroxypropylcellulose, carboxymethylcellulose, bentonites or magnesium aluminum silicates according to the teachings of Wheeler. One having ordinary skill in the art would have been motivated to substitute alginate gums or their salts, guar gum, locust bean gum, xanthan gum, gum acacia, gelatin, hydroxymethylcellulose or its sodium salt, hydroxyethyl cellulose, hydroxypropylcellulose, carboxymethylcellulose, bentonites or magnesium aluminum silicates gelling agent with another gelling agent such as polyacryldimethyltauramide-co-vinylformamide (Aristoflex) with the expectation that the aqueous composition will be gelled.

It is also known in the art that xanthan gum and ARISTOFLEX AVC are thickening agents (see column 38, lines 25-32 of US 6,294,186). Xanthan gum is one of the gelling/thickening agents of Wheeler (page 4, first full paragraph). Since xanthan gum and ARISTOFLEX AVC have been recognized in the art to be thickening agents, one thickening agent can be used in place of the other to obtain the same gelling or thickening effect. Therefore, taking the teachings of Wheeler and Beerse, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success to substitute one thickening agent for another, in this case ARISTOFLEX AVC can be substituted for xanthan gum.

Response to Arguments

4. Appellant's arguments filed 4/13/2009 have been fully considered but they are not persuasive.

5. Initially applicant poses the question whether one of ordinary skill in the art at the time the invention was made would have reasonably expected that substitution of the sulfonic acid gellant taught in Clariant or US '186 for conventional gellant described in the WO 97/32559 publication "would have placed the present invention into the possession of those skilled in the art." The answer is YES, one having ordinary skill in the art at the time the invention was made would have reasonably expected that one gellant can be used in place of the other to effect gelling of a composition such as the one disclosed in the WO 97/32559 publication. The gellant amount in the WO 97/32559 publication is at 0.5-20% (page 4, 1st full para.) and any other gellant may be used in those amounts to effect thickening or gelling with the disclosed amount encompassing the amount in the range recited. Surfactant in WO 97/32559 publication is at 0.05 to 0.5% (page 3, lines 4-7 of the 4th full paragraph) with the 0.05 to 0.5% being less than 1 percent as recited in the claims. The pH advocated in the Wheeler reference is less than or equal to 7 meeting the requirements of the claims. The composition of Wheeler also contains salt (1st full para. of page 5) and it would be obvious to use amounts of salts that would provide the desired pearlescence and luster to the gelled composition. The one difference is the type of gellant and as described in the rejections above, that xanthan gum and Aristoflex AVC, which is the specific gelling agent now recited in the claims as polyacryldimethyltauramide-co-vinylformamide, are known gelling agents. It would thus be reasonable to substitute one for the other with the expectation of gelling the composition as desired. Since the composition of

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Wheeler is gelled by the addition of the gelling agent, the method of thickening the composition is also met. 35 USC 103 prescribes that the focus of the enquiry is whether the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art. In the present case the result of substituting one thickening agent (gellant) for another is a predictable thickening of the composition and as such a substitution would have been obvious at the time the invention was made.

6. Wheeler: Applicant argues that the Wheeler reference, WO 97/32559 publication, fails to teach or suggest applicant's invention of surprising and advantageously unexpected use of the particular gellant in a bi-liquid composition because Wheeler does not teach composition comprising the particular gellant and that the examiner advanced no basis for suggesting the substitution of ammonium poly(acryldimethyltauramide-co-vinylformamide) for the other gellants/thickening agents of Wheeler. The examiner disagrees. The composition of Wheeler is a bi-liquid foam containing oils, thickening/gelling agent, surfactant and salts and the pH of the composition is suggested to be less than or equal to 7. The difference is ammonium poly(acryldimethyltauramide-co-vinylformamide) v. any of the thickening or gelling agents in Wheeler, namely, alginate gums or their salts, guar gum, locust bean gum, xanthan gum, gum acacia, gelatin, hydroxymethylcellulose or its sodium salt, hydroxyethyl- cellulose, hydroxypropylcellulose, carboxymethylcellulose, bentonites, magnesium aluminum silicates, "Carbomers" (salts of cross-linked polymers of acrylic acid), or glyceryl polymethacrylates or their dispersions in glycols, or any appropriate mixture of any of these polymers and gums in an amount between 0.05-20% (page 4, first full paragraph). The Clariant reference teaches the use

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of Aristoflex for thickening oil-in-water emulsions or aqueous systems at low pHs and the '186 Patent teaches the equivalence of Aristoflex and other thickening agents such as xanthan gum. The rationale is that simple substitution of one known element for another to obtain predictable results is *prima facie*, and in this case the substitution of the Aristoflex, which is ammonium poly(acryldimethyltauramide-co-vinylformamide) according to applicant's specification at para. [0006] of the published application, for any of the gelling agents of Wheeler would result in predictable gelling of the composition. The rejection is that the claimed invention would have been obvious at the time the invention was made and not that the composition was anticipated by Wheeler.

7. Clariant: Applicant argues that the Clariant reference failed to disclose or suggest gelling agent in the amount of 0.01 to 10% to thicken oil-containing bi-liquid foam containing salt in amount of 1-10% and a composition containing less than 1% surfactant. But, the Clariant reference was relied upon for teaching that oil containing or aqueous compositions can be thickened with the sulfonic acid gellant and not for what the primary reference teaches, that is, bi-liquid foam composition comprising gelling agent, surfactant, oil and salts and the response in paragraph 5 above is incorporated here as it relates to the % amounts of the ingredients in the bi-liquid foam. With regards to applicant's argument that the Clariant reference does not contemplate the difficulty in the prior art of gelling low pH aqueous compositions containing significant amounts of salt, it is noted that the Wheeler reference teaches bi-liquid foam compositions that are thickened or gelled at pH of less than or equal to 7, with the composition containing salts. pH of less than 7 as disclosed in Wheeler meets what claim 1 prescribes, that is, pH of less than 7. Thus, aqueous compositions containing salts and have been thickened by

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gelling agents in wheeler. The Clariant reference was not used to solve a seeming problem that has been solved by Wheeler, even if by another thickening agent.

8. US '186: Applicant argues that the '186 patent describes antimicrobial compositions that optionally comprises thickening agents from a laundry list of thickening agents so that applicant argues that because the '186 patent makes no distinction among thickening agents, the patent does not recognize the problem that was solved by the instant invention. The examiner disagrees with the applicant that the '186 patent must recognize the problem that needed to be solved because a bi-liquid foam composition comprising oil, surfactant, and salts has been thickened at pH of less than 7 (Wheeler) and also thickening agents such as Aristoflex are used in compositions and as thickening agents (Clariant), the role of Aristoflex and xanthan gum must intrinsically be to thicken. Furthermore, applicant appears to admit that though, a laundry list of thickening agents are listed in the '186 patent, Aristoflex and xanthan gum are recognized as equivalent as thickening agents. The lack of distinction between the thickening agents by the '186 patent suggests that the thickening agents are art recognized equivalents as thickening agents.

9. Pages 9-13 of the remarks deal with supposed negative teaching of US 6,197,318 regarding Carbopols and salts and applicant's contention that because the examiner used a reference to reject the claims, applicant is also entitled to use a reference that was not used in the rejections to show the composition disclosed in the reference is not tenable. The examiner will respond to these objections page by page for applicant's convenience and clarity.

10. Page 9 of remarks, 1st full paragraph: Applicant argues that Wheeler (WO 97/32559) in view of Clariant or Beerse ('186) does not render obvious the present invention because

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"although one of ordinary skill in the art might have attempted a simple substitution of one known gellant for another, expecting to obtain predictable results (i.e. gelling of the aqueous phase of a low pH bi-liquid-containing dispersion), the person of ordinary skill in the art could not have predicted that the polymeric sulfonic acid gellant could be used to stably gel the aqueous phase in a bi-liquid containing aqueous composition, where the aqueous phase has a pH of less than 7 and a significant salt presence, using less than 1 percent by weight of surfactant, based on the total weight of the composition."

Response to para. 10 above: The examiner disagrees with applicant's argument in this section because as described in the rejections and in paragraph 5 above, it is reasonable to expect that substituting the sulfonic acid gellant for any of the gellants in Wheeler will produce the expected gelling and further the sulfonic acid gelling agent and the agents in Wheeler are all gelling agents (see page 4, 1st full paragraph). Wheeler's composition stable (see page 3, 3rd full paragraph).

11. Page 9 of remarks, 2nd full paragraph: Applicant argues that the skilled artisan at the time the invention was made would have expected the presence of salts in the composition to affect the viscosity response of the gellant and that salts would destabilize the gel in the absence of significant level of surfactant and that US 6,197,318 at column 11, line 65 to column 14, line 17 demonstrate that Carbopol, which is used as a gellant in Wheeler, are known to demonstrate poor salt tolerance when incorporated into the external use compositions containing salts, that 6,197,318 uses xyloglucan with the Carbopol to impart stability; it is unexpected that sulfonic acid gelling agent would be unaffected by the presence of salts in the composition; that example

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2 of Wheeler uses sodium chloride as a thickening agent; and in conclusion applicant rebuts examiners suggestion that one thickening agent can be used in place of the other.

Response to para 11 above: Wheeler does not list sodium chloride as a gelling/thickening agent. The section applicant relies on says that “the mixture was adjusted to pH 5.5 by the addition of extra citric acid, and to a viscosity of 9,000 centipoise by the addition of extra sodium chloride, and finally a suitable coloring agent was added.” This section did not disclose the initial viscosity before the addition of extra sodium chloride in order to ascertain if Wheeler used sodium chloride as a gellant agent or to ascertain if there were viscosity increases in order to arrive at the conclusion that sodium chloride is a gelling agent. Gleaning from that section of Wheeler and the viscosity value, it is not persuasive to conclude that sodium chloride is a gelling agent especially the fact that Wheeler did not list sodium chloride as a gelling agent. US 6,197,318 was not used as art to reject the claims. However, in order to satisfy applicant's request to consider US 6,197,318 as art that discourages the skilled artisan from using the disclosure of Wheeler, column 13, lines 1-16, which relates carbovinyl polymers with salt is reproduced below for applicant's benefit:

--- “Japanese Patent Application Laid-Open (kokai) No. 70264/1997 discloses an external-use composition which contains a complex of xyloglucan and a specific β -glucan. The external-use composition containing the complex may have "a sensation like that caused by coating with film" in use, since the complex, which complex is produced in order to effectively increase the viscosity of xyloglucan, is incorporated into the composition. In order to eliminate the above sensation of the composition containing the complex, a large amount of carboxyvinylpolymers, which polymers are incorporated in the external-use composition of the

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fourth mode of the present invention, must be incorporated into the above composition, since the viscosity of the complex is very high. However, a large amount of the polymers may cause the external-use composition to have poor salt tolerance.”----

Carbovinyl polymers are identified as Carbopols and PEMULEN in column 14, lines 38-40 of the 6,197,318. But, it is clear that the 6,197,318 patent is concerned with large amounts of the polymer, Carbopol to have poor salt tolerance. However, it is also clear that Wheeler discloses use of other gelling agents in amounts in the range of 0.05 to 20% and more particularly 0.2 to 1% and these amounts do not appear to represent large amounts of polymers and US 6,197,318 did not define what large amount would be. The invention of the 6,197,318 is directed to compositions comprising xyloglucan and ultraviolet shielding agent in all the 5 embodiments and further contains thickening agents in embodiments 2-5. Further also, Wheeler teaches use of other gelling agents besides Carbopols, and Xanthan gum is the second gum in the list of gums named (see page, 1st full para.). There is also no teaching in Wheeler that salts negatively impact the bi-liquid foams. Thus, the skilled artisan would not be discouraged away from the Wheeler reference.

12. Page 10 of remarks:

a) 1st full paragraph: Applicant argues that showing that tolerance for thickeners disclosed in Wheeler other than the Carbopol would be burdensome and that applicant urges that all the examples in Wheeler employ Carbopol except for example 2 that utilizes sodium chloride as thickening agent; that applicant's point is that the Wheeler reference does not recognize that conventional thickeners such as Carbopol are sensitive to salts.

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Response to 12 a) above: The examiner does not find where sodium chloride is listed as a thickener in Wheeler. Secondly, applicant acknowledges that Wheeler names thickeners other than Carbopol and the fact that Wheeler uses Carbopol in the examples do not limit the disclosure to the examples when there is disclosure in the Wheeler reference for other suitable thickeners. A reference is not limited to the working examples, but the reference must be evaluated for what it teaches those or ordinary skill in the art.

b) 2nd and 3rd full paragraphs: Applicant argues that in light of the destabilizing nature of salts, the examiners suggestion that it would be obvious to use appropriate amount of salt that would provide desired pearlescence and luster to gelled compositions is technically unsound and that the examiner provided no basis for that conjecture. Applicant thus says that Examples 1-3 of Wheeler teaches pH of less than 7, the composition lacks sulfonic acid gellant and also fails to include from about 1 to about 10% salt.

Response to 12 b) above: Applicant is forcefully attempting to limit thickener in the Wheeler's reference to carbopol when there is a clear disclosure that other thickeners can be used such as gums. A reference is not limited to the examples. The examiner agrees that Wheeler does not use sulfonic acid gellants and that is the reason for using secondary reference to show that sulfonic acid gellants are known to be used to gel aqueous compositions and compositions containing oils. Further, applicant acknowledges that xanthan gum and Aristoflex, the sulfonic acid gellant are equivalent because the '186 patent made no distinction between the thickeners (see applicants remark at page 9, lines 2-4). With regards to luster and pearlescence, the rationale came from the Wheeler reference itself because salts are listed as opacifying or

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pearlising agents (see page 5, 1st full paragraph). Thus, what may be technically unsound to applicant is specifically disclosed in Wheeler.

c) Page 10 4th full paragraph: Applicant argues that substituting Aristoflex for the gellant in Example 1 of Wheeler would not result in the "Appellant's" composition because the present specification set out to formulate stable water based gel type compositions while achieving maximum incorporation of actives.

Response to 12 c) above: The Wheeler reference is not limited to example 1. One of Wheelers goal is to formulate stable oil-based bi-liquid foam (see page 3, 3rd full paragraph). Wheeler does not disclose that active agents cannot be incorporated in the composition, rather, Wheeler suggests that active ingredient may be present in either the aqueous or oily phase (page 3, 4th full paragraph). The claims have also not recited active agents.

13. Page 11 including lines 1-7 of page 12: Applicant's arguments on page 11 are directed to examples 2 and 3 of the Wheeler reference and applicant's calculation of how much surfactant is present in each of the example.

Response to 13 above: While the examples may teach 41 wt% surfactant according to applicant's calculation, Wheeler discloses that surfactant is present in amounts of from 0.05 to 0.5% (see page 3, 4th full paragraph); specifically, Wheeler contemplates formulations having low levels of surfactants (page 4, 3rd full paragraph) and specifically teaches that the bi-liquid foams of the disclosed compositions do not possess the disadvantage of skin irritations of prior art compositions because the disclosed composition have low levels of surfactant (see page 3, second full paragraph). Therefore, the examiner does not see how the surfactant in the

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composition of Wheeler is calculated by applicant to be at 41%, which is 82 times higher than the upper limit contemplated.

14. Page 12, 1st full paragraph to page 13 1st full paragraph:

15. d) Applicant argues that Wheeler's composition is not stabilized by less than 1% surfactant, does not contain sulfonic acid gellant, the pH is not less than 7 and the amount of salt is not present at 1-10%;

16. e) Applicant argues that it would not have been predictable to use Aristoflex in place of the gellant in Wheeler at low pH's and that the declaration of Harrison and Matathia-Jacobs filed demonstrate that under certain conditions, gellants such as Carbomers/Carbopol as well as other gellants recommended by WO 97/32559 do not provide homogeneous stable aesthetically and commercially acceptable product; that it is improper for the examiner to refer to documents dating back to 2003 and 2004.

Response to 14 d above: Wheeler teaches compositions having low level surfactant (see page 3, 4th full paragraph and page 4, 3rd full paragraph); the compositions are anticipated to have pH's of less than 7 and since Wheeler exemplifies compositions that are adjusted to pH 5.5 (example 2), pH 6.5 (examples 1, 3) and pH 7 (example 4), which suggests that pH of the solutions to be at less than or equal to 7 such that it would have been obvious to prepare the compositions at pH of less than or equal to 7 meeting the requirements of claims 1, 12 and 19. Wheeler suggest acidic pHs by adjusting the compositions in examples 1-6 to pHs of less than 7 of 7. The rejection was clear that Wheeler does not teach sulfonic acid gellants and that is why a secondary reference was used to remedy that deficiency. The broad teaching of salt meets the

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requirement for broad recitation of salt in the claims and it would be obvious to use appropriate amount of salt that would be provide desired pearlescence to the gelled composition.

Response to 14 e above: The Clariant reference describes commercially available gellant product, ammonium poly(acryldimethyltauramide-co-vinylformamide), also known as AVC, for gelling or thickening aqueous systems at low pHs.

17. Declaration filed 11/1/2003 and 3/18/2003 (see Evidence appendix, page 16 of the Brief filed 08/01/09) and submitted with the Appeal Brief filed 8/01/2008 had been previous addressed in the office action of 1/30/2004. But, in light of applicant's objection to reference to the office action of 1/30/2004 as in applicant's words "documents dating back to 2003 and 2004," the examiner respectfully provides the response below to address the declarations filed 11/1/2003 and 3/18/2003 and submitted with the Appeal Brief filed 8/01/2008 (see Evidence appendix, page 16 of the Brief filed 08/01/09) in hopes to satisfy applicant. It is also noted that the declaration by Michelle Matathia Jacobs was stamped received on 10/24/2003 and entered filed 11/1/2003 and not the date of 8/27/01 stated in the Evidence appendix, page 16 of the Appeal Brief filed 8/1/08. It is further noted that the application was filed 11/26/2001.

18. Declaration under 37 CFR 1.132 by Michelle Matathia Jacobs filed 11/1/2003 and submitted with Appeal Brief of 08/01/2008 (see page 16 of Appeal brief filed 08/01/08):

19. The declaration under 37 CFR 1.132 filed 11/1/2003 and re-submitted 08/01/08 is insufficient to overcome the rejection of claims 1, 3, 6-10, 12-15, 18, 19 and 21 based upon Wheeler (WO 97/32559) in view of Clariant product brochure or in view of Beerse et al. (US 6,294,186) as set forth in the last Office action because: The data in paragraph 5 of the declaration does not provide the composition used in the data collection, rather concentrations of

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Carbopol at 10%, 0.3% and 0.5%; hydroxyethylcellulose at 0.25%, 0.5%, 0.75% and 1%; algin or sodium alginate at 0.5%; starch at 6% and 31.24%; and then AVC (Aristoflex) at 1% and 2%.

Claim 1 is a composition that comprises AVC at from about 0.01% to about 10%, oil, surfactant and salt. There is no indication that the composition tested is a bi-liquid form; the pH of the composition tested is not named; there is no mention of surfactant and salt and oil. Further, the AVC has no points outside of the claimed range. On the whole, the data presented is not from composition that is commensurate in scope with the claimed composition.

20. Declaration under 37 CFR 1.132 by James T. Harrison filed 3/18/2003 and re-submitted with Appeal Brief of 08/01/2008 (see page 16 of Appeal brief filed 08/01/08):

21. The declaration under 37 CFR 1.132 filed 3/18/03 and re-submitted 8/01/08 is insufficient to overcome the rejection of claims 1, 3, 6-10, 12-15, 18, 19 and 21 based upon Wheeler (WO 97/32559) in view of Clariant product brochure or in view of Beerse et al. (US 6,294,186) as set forth in the last Office action because: Formula B identified by declarant as the claimed invention uses 0.08% AVC, 0.02% sodium chloride and specific combination of oils and specific surfactants specific antimicrobial agent, while claim 1 comprises from about 0.01% to about 10% AVC, oil, salt at from about 1 to about 10% and less than 1% surfactant. 0.08% AVC is not representative of from about 0.01 to about 10%; sodium chloride is not recited as salt in claim 1. Sequence 6-20 in formula B, which is the claimed formula, is water while in the comparable formula A that represents Wheeler, it is caustic soda. Thus the declaration compares two compositions, one using sodium hydroxide representing the composition of Wheeler and the other free of sodium hydroxide representing the claimed composition. The data presented use single points for AVC and carbopol. Furthermore, in Wheeler, carbopol is

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not the only gellant contemplated for use. On the whole the composition or formula B from which the data is generated is not commensurate with the scope of claim 1 making the declaration non-commensurate with the scope of the claims.

22. Thus with respect to the declaration by James T. Harris, applicant may claim formula B of Appendix A, the composition applicant/declarant shows to produce the unexpected result.

23. Claims 1, 3-10, 12-16, 18, 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wheeler (WO 97/32559) in view of Beerse et al. (US 6,294,186) and further in view of Vatter et al. (US 6,224,888) or France et al (US 4,184,978) for reasons of record and modified herein to remove canceled claims 2 and 20 from the rejection.

24. Wheeler in view of Beerse has been shown above to render obvious claims 1, 3, 6-10, 12-15, 18, 19 and 21. The composition of Wheeler is a cosmetic that can be delivered to the skin and hair (2nd, 3rd and 4th full paragraphs of page 5) to cleansing and conditioning. However, the composition of Wheeler in view of Beerse does not contain the salts recited in claims 4, 5 and 16. But these salts of alpha- or beta- hydroxy acids are known in the art to be used in cosmetic compositions.

25. For example, sodium lactate and salts of lactic acid or alpha hydroxy acids are known moisturizers for skin care (see column 12, lines 35, 62-67 of US 6,224,888). Therefore, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success that adding the moisturizers such of the salts of lactic acid would effectively aid in moisturizing and conditioning of the skin and hair. It is also known in the art that lactic acid and its salts are found naturally in the skin environment to maintain proper pH

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and moisturizing levels and known to be included in cosmetics (see column 5, lines 45-48 of US 4,148,978). Therefore, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success that adding the moisturizers such of the salts of lactic acid would effectively aid in moisturizing and maintaining the normal pH of the skin and hair.

Response to Arguments

26. Applicant's arguments filed 4/13/2009 have been fully considered but they are not persuasive.

27. Applicant argues that the combination of Wheeler '559 and Clariant or the '186 patent fails to teach the present inventive composition at pH of less than 7 and comprising ammonium poly(acryldimethyltauramide-co-vinylformamide (AVC or Aristoflex), 1-10% salt, less than 1% surfactant. The examiner disagrees and a response to this argument has been previous given above and incorporated here.

28. Applicant argues that US '888 fails to recognize the problem solved by the present invention of formulating aesthetically appealing (clear and creamy) water based , low pH gel, while maximum incorporation of actives is achieved in the absence of significant amounts of surfactant and as such cannot cure the deficiencies of Wheeler.

Response: The examiner notes that Wheeler in combination with the Clariant or US '186 has been described above to disclose water based bi-liquid aqueous gel composition at low pH in the presence of salt and in the presence of less than 1% surfactant and ammonium poly(acryldimethyltauramide-co-vinylformamide (AVC or Aristoflex). The '888 patent was relied upon to provide what is missing in the combined formulation of Wheeler and Clariant or

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Wheeler and the '186 patent as required by claims 4, 5 and 16, that is, sodium lactate and salts of lactic acid or alpha hydroxy acids are known moisturizers for skin care (see column 12, lines 35, 62-67 of US 6,224,888), which is the limitations in claims 4, 5 and 16. Therefore, the '888 patent cures the deficiencies of the combined formulation of Wheeler and Clariant or Wheeler and the '186 patent with respect to claims 4, 5 and 16.

29. Applicant also argues that the '978 patent fails to recognize the problem solved by the present invention of formulating aesthetically appealing (clear and creamy) water based , low pH gel, while maximum incorporation of actives is achieved in the absence of significant amounts of surfactant and as such cannot cure the deficiencies of Wheeler and the '186 patent.

Response: The examiner disagrees and notes that Wheeler in combination with the Clariant or US '186 has been described above to disclose water based bi-liquid aqueous gel composition at low pH in the presence of salt and in the presence of less than 1% surfactant and ammonium poly(acryldimethyltauramide-co-vinylformamide (AVC or Aristoflex). The '978 patent is relied upon for teaching that lactic acid and its salts are found naturally in the skin environment to maintain proper pH and moisturizing levels and known to be included in cosmetics (see column 5, lines 45-48 of US 4,148,978), which is the limitation in claims 4, 5 and 6 that is not taught by the combined references. Therefore, the '978 patent cures the deficiencies of the combined formulation of Wheeler and Clariant or Wheeler and the '186 patent with respect to claims 4, 5 and 16.

No claim is allowed.

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30. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Examiner, Art Unit 1618